

## CLAIMS

1. A method for measuring an affinity substance, which comprises the steps of:
  - (1) mixing carrier particles with an affinity substance to be measured and applying a voltage pulse, wherein the carrier particles are bound to a binding partner having an activity to bind to the affinity substance; or
  - (1') mixing carrier particles with an agglutination reagent component and an affinity substance to be measured, and applying a voltage pulse, wherein the carrier particles are bound to a binding partner having an activity to bind to the affinity substance, and wherein the affinity substance inhibits agglutination of the carrier particles caused by the agglutination reagent;
  - (2) counting agglutinates of carrier particles formed upon the binding of the affinity substance to be measured, or unagglutinated carrier particles which did not bound to the affinity substance, or both, based on their three-dimensional information as an indicator after step (1); or
  - (2') counting agglutinates of carrier particles formed upon the binding of the agglutination reagent, or carrier particles whose agglutination was inhibited through the binding of the affinity substance to be measured, or both based on their three-dimensional information as an indicator after step (1'); and
  - (3) determining the level of the substance to be measured based on either or both of the level of agglutinate formation and the level of unagglutinated carrier particles after step (2) or (2').
2. The method of claim 1, wherein the three-dimensional information of agglutinates or carrier particles is physically measured in step (2) or (2').
3. The method of claim 2, wherein the method of physically measuring the three-dimensional information is a method selected from the group consisting of electric resistance method, laser diffraction/scattering method, and three-dimensional image analysis method.
4. The method of claim 1, wherein the voltage pulse is an alternating current voltage pulse.
5. The method of claim 1, which comprises counting the carrier particles after the electric field is removed in step (2) or (2').
6. The method of claim 5, which further comprises the step of diluting the carrier particles after the electric field is removed in step (2) or (2').
7. The method of claim 1, which comprises applying voltage pulses several times.

8. The method of claim 7, which comprises the step of applying voltage pulses, dispersing the carrier particles, and applying voltage pulses again.
- 5 9. The method of claim 7, wherein the voltage pulses are applied from different directions.
10. The method of claim 1, wherein the mean particle size of carrier particles is 1  $\mu\text{m}$  or greater.
- 10 11. The method of claim 10, wherein the mean particle size of carrier particles is in the range of 1 to 20  $\mu\text{m}$ .
12. A device for measuring an affinity substance, which comprises:
- 15 (a) a space containing carrier particles and an affinity substance to be measured, wherein the carrier particles are bound to a binding partner having an activity to bind to the affinity substance;
- (b) electrodes for applying a voltage pulse to the carrier particles in the space; and
- (c) a device for counting agglutinates formed through agglutination of carrier particles, or unagglutinated carrier particles in the space, or both, using their three-dimensional information
- 20 as an indicator.
13. The device of claim 12, wherein the device of (c) is a means for physically measuring three-dimensional information.
- 25 14. The device of claim 13, wherein the device for physically measuring the three-dimensional information is a means for physically measuring three-dimensional information using a method selected from the group consisting of electric resistance method, laser diffraction/scattering method, and three-dimensional image analysis method.
- 30 15. The device of claim 12, which comprises at least two pairs of electrodes for applying the voltage pulse.
16. The device of claim 12, which comprises a means for moving the electrodes to apply the voltage pulse and which can supply an electric field from different directions with respect to the
- 35 space.